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A randomised controlled trial of three psychological treatments for anorexia nervosa

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Abstract

Background: There is a lack of evidence pointing to the efficacy of any specific psychotherapy for adults with anorexia nervosa (AN). The aim of this study was to compare three psychological treatments for AN: Specialist Supportive Clinical Management (SSCM), Maudsley Model Anorexia Nervosa Treatment for Adults (MANTRA) and Enhanced Cognitive Behavioural Therapy (CBT-E).

Method: A multi-centre randomised controlled trial. Outcomes were assessed at pre-, mid-, and post-treatment and 6- and 12-month follow-up by researchers blind to treatment allocation. All analyses were intention-to-treat. One hundred and twenty individuals meeting diagnostic criteria for AN were recruited from outpatient treatment settings in three Australian cities. Participants attended 25-40 sessions over a 10 month period. Primary outcomes were BMI and eating disorder psychopathology. Secondary outcomes were measures of depression, anxiety, stress and psychosocial impairment.

Results: Treatment was completed by 60% of participants and 52.5% completed 12 month follow-up. Completion rates did not differ between treatments. There were no significant differences between the treatments on continuous outcomes; all resulted in clinically significant improvements in BMI, eating disorder psychopathology, general psychopathology and psychosocial impairment that were maintained over 12 month follow-up. There were no significant differences between the treatments with regard to the achievement of a healthy weight (mean = 50%) or remission (mean = 28.3%) at 12 month follow-up.

Conclusion: The findings add to the evidence base for these three psychological treatments for adults with AN but the results underscore the need for continued efforts to improve outpatient treatments for this disorder.

Trial Registration: Australian New Zealand Clinical Trials Registry (ACTRN
12611000725965) <http://www.anzctr.org.au/>

Anorexia Nervosa (AN) is a serious mental disorder that has a substantial effect on psychological, physical, social and vocational functioning (Arcelus et al., 2011; Mitchison et al., 2013; Paxton et al., 2012; Steinhausen, 2002; Stice et al., 2013; Treasure et al., 2001). It is notoriously difficult to treat and tends to run a chronic course (Steinhausen, 2002; Stice et al., 2013). Progress has been made in treating younger patients using family-based approaches (le Grange and Eisler, 2009) but there is little convincing evidence to suggest that any psychological or pharmacological treatment consistently produces good outcomes for adults with AN. Nor is there evidence pointing to the superiority of any one treatment above another (Hay et al., 2015; National Collaborating Centre for Mental Health, 2004; Watson and Bulik, 2013; Zipfel et al., 2015).

In the past decade two new psychological treatments have been developed for, and evaluated with, AN; the Maudsley Model Anorexia Nervosa Treatment for Adults (MANTRA) (Schmidt and Treasure, 2006) and Enhanced Cognitive Behavioural Therapy (CBT-E) (Fairburn, 2008). MANTRA targets factors specific to the cognitive-interpersonal theory of the maintenance of AN. CBT-E is based on a cognitive behavioural theory of the processes maintaining eating disorder psychopathology, and is a trans-diagnostic treatment designed for all eating disorders (Fairburn et al., 2003; Fairburn, 2008).

MANTRA has been the focus of two randomised controlled trials (RCTs) (Schmidt et al., 2012, 2015) involving 72 and 142 participants respectively, both of which involved a comparison with Specialist Supportive Clinical Management (SSCM) (McIntosh et al., 2005, 2010). SSCM is derived from the typical supportive approach of specialists to the management of AN. Both studies showed sustained improvements in eating disorder features and weight and no significant differences between MANTRA and SSCM (McIntosh et al., 2005; Schmidt et al., 2012; Touyz et al., 2013). In the first of these RCTs (Schmidt et al., 2012) the mean BMI increase from baseline to 12 months post-randomization (end of

treatment) for MANTRA and SSCM respectively was 1.37 kg/m² and 1.22 kg/m². In the later multi-centre RCT (the MOSAIC Study; Schmidt et al., 2015), the mean BMI increase at the same time point was 1.75 kg/m² for MANTRA and 1.36 kg/m² for SSCM. These improvements in BMI increased to 2.25 kg/m² and 2.16 kg/m² at 24 months post-randomisation (Schmidt et al., 2016).

The use of outpatient CBT-E in AN has been the focus of a three-centre cohort study involving adults (Fairburn, 2013; N=99) and a further cohort study involving adolescents (Dalle Grave et al., 2013; N=46). These studies have reported positive and equivalent findings across the treatment centres. In the Fairburn cohort study, mean BMI increased by 1.8 kg/m² from baseline to end of treatment (a period of 10 months) and this increase was maintained (1.7 kg/m²) over a 60 week period of follow-up (i.e., 24 months post-randomisation). A variant of CBT-E has been compared with focal psychodynamic therapy (FPT) and "optimized treatment as usual" (TAU) in a multi-centre RCT involving 242 adults (the ANTOP Study). The improvements obtained with the three treatments were modest and there were no significant differences among them (mean BMI increase by end of 10 months of treatment of 0.73 kg/m² for FPT; 0.93 kg/m² for CBT-E and 0.69 kg/m² for TAU and at 12 months follow-up [22 months post-randomisation] 1.64 kg/m² for FPT; 1.30 kg/m² for CBT-E and 1.22 kg/m² for TAU). It therefore appears that, regardless of the type of outpatient therapy, a weight gain between 0.69-1.80 kg/m² over a 12-month period can be expected, rising to between 1.22 and 2.25 kg/m² at 24 months. CBT-E has not previously been compared with MANTRA or SSCM.

The aim of the current trial was to compare the efficacy of these three psychotherapies for AN. The primary outcomes were BMI and global eating disorder psychopathology, and secondary outcomes were measures of depression, anxiety, stress and psychosocial impairment. It was hypothesized that CBT-E and MANTRA would be superior to SSCM in

terms of weight gain and eating disorder psychopathology as they both focus on specific maintaining processes.

Method

Study Overview

The Strong Without Anorexia Nervosa (SWAN) study was a multi-centre RCT involving five treatment centres from three Australian States. Across all three treatments participants were offered 25-40 fifty-minute sessions over a 10 month period. The number of sessions allocated was titrated according to the participant's initial BMI ($< 16 = 40$ sessions, $16 \geq 17.5 = 30$ sessions, $17.5 \geq 18.5 = 25$ sessions) to allow for the amount of time required to achieve weight regain. Up to four additional sessions with a close other/parent/partner were permitted. Participants were also able to have up to six booster sessions in the 12 months post-treatment. Monitoring of physical risk was conducted by participants' general practitioners. If BMI fell below 14 or medical instability emerged, treatment was suspended for up to 21 days for inpatient treatment. If a participant was unable to rejoin the trial after 21 days, he/she was withdrawn from the study and the last data points were included in the intention-to-treat analyses. Outcomes were assessed at baseline, mid-treatment, end of treatment, and at 6 and 12 months post-treatment by researchers blind to treatment allocation. Ethical approval was obtained from Human Research Ethics Committees at each site.

Recruitment

Participants were recruited directly from the community (in response to media advertisements) and from treatment centres in Perth (University of Western Australia; Centre for Clinical Interventions); Adelaide (Flinders University Services for Eating Disorders) and Sydney (Sydney University; Western Sydney University). Appropriate self-referrals and

consecutive referred outpatients were assessed and offered participation if they met the following inclusion criteria: BMI ≥ 14.0 and < 18.5 ; 17 years or over; meeting diagnostic criteria A and B for AN in the Diagnostic and Statistical Manual of Mental Disorders, Fourth edition Revised (DSM-IV-TR) (Association, 2000). These criteria correspond to the current DSM-5 diagnostic criteria for AN (American Psychiatric Association, 2012). Exclusion criteria were: severe physical or mental illness such that outpatient treatment was inappropriate, current severe substance dependence, current use of atypical antipsychotics because of the weight gain properties of these drugs, not being available to complete the full course of treatment, other active psychotherapy focusing on AN.

Interventions

Maudsley Model of Anorexia Nervosa Treatment for Adults (MANTRA) is a formulation-based treatment accompanied by a patient workbook. Treatment is individually tailored to match the clinical symptoms, personality traits and the neuropsychological profile of patients (Schmidt et al., 2013, 2014). It effects change through targeting four putative maintaining factors (the person's thinking and emotional/relational style, close others' responses to the illness, and beliefs about the utility of AN in the person's life; Treasure and Schmidt, 2013).

Enhanced Cognitive Behaviour Therapy (CBT-E) for underweight patients has three phases (Fairburn et al., 2008) and is based on the transdiagnostic maintenance model of eating disorders (Fairburn et al., 2003). In the first, the emphasis is on increasing patients' motivation to change. Then patients are helped to regain weight while at the same time tackle their eating disorder psychopathology including their extreme concerns about shape and weight. In the final phase the emphasis is on helping them maintain the changes obtained while developing strategies for correcting any setbacks. The focused version of CBT-E was used unless lack of progress indicated the use of the broad version.

Specialist Supportive Clinical Management (SSCM) combines clinical management and supportive psychotherapy within sessions emphasising normalization of eating and restoration of weight, specialist psychoeducation and focus on other key symptoms, such as vomiting or overexercising. The remainder of the sessions focus on content dictated by the patient (McIntosh et al., 2005, 2010; Schmidt et al., 2015).

Therapists

Therapists (N=8) were psychologists with at least 2 years' experience using specialized psychological treatments for eating disorders. They delivered all three treatments and received training in them in a series of 2 day workshops from the treatment developers (VM [SSCM]; US, JT [MANTRA] and CGF [CBT-E]). Therapists received twice-weekly supervision provided by the Australian chief investigators (SB, TW, PH). One supervision session was site-specific and the other was treatment specific involving all therapists, using teleconferencing facilities. Treatment developers were consulted when necessary. All treatment sessions were audio-recorded and therapist adherence was found to be excellent (Andony et al., 2015). The treatments were highly distinguishable and no inter-site differences in therapist adherence were observed (Andony et al., 2015).

Assessment and outcome measures

Assessment incorporated semi-structured clinical interviews and self-report questionnaires. The Mini International Neuropsychiatric Interview (Sheehan et al., 1998) was used to assess other current Axis 1 disorders. Outcomes included BMI, eating disorder features, general psychopathology, associated functioning, and a range of additional measures to assess the goodness of fit of the theories associated with the different therapies.

Eating disorder psychopathology was measured using the global subscale of the Eating Disorder Examination (EDE; Fairburn and Wilson, 1993) an investigator-based structured interview. Other self-reported outcomes included the short form of the Depression, Anxiety and Stress Scale (DASS; Lovibond and Lovibond, 1995) and the Clinical Impairment Questionnaire (CIA; Fairburn et al., 2009), a measure of the severity of psychosocial impairment due to eating disorder features. Participants' ratings of treatment credibility and the likely effectiveness of treatment were assessed at mid-treatment using a 4 item Credibility and Expectations Questionnaire (CEQ; Borkovec and Nau, 1972; Devilly and Borkovec, 2000) adapted for this study (Carter et al., 2012). Items were rated using a 9 point Likert scale and scores were summed and divided by 4. Treatment credibility, acceptability and perceived effectiveness was also assessed at post-treatment using the CEQ (worded in the past tense).

Randomisation

The generation and implementation of the randomisation sequence was conducted, independently, by the study coordinator (KA). Participant randomisation followed CONSORT guidelines (Boutron et al., 2008) and made use of stratification with blocking, to ensure that treatment groups were generated with approximately equal numbers. Randomisation was stratified by site and BMI ($BMI < 17.5$; $BMI \geq 17.5$). Randomisation codes were generated electronically and then placed in sequentially numbered, sealed, opaque envelopes, to be opened at the point of randomisation (following initial assessment).

Data analyses

Sample size calculations were performed for the primary outcome hypotheses on an intention-to-treat basis. Power calculations were based upon determining power for longitudinal designs with attrition (Hedeker et al., 1999) with a two-tailed alpha of .05, five

assessment points (with baseline serving as a covariate), attrition rates of 40%, and a fixed autoregressive coefficient of .40. An enrolled sample size of 40 per group would provide 80% power at two-sided $p < .05$ to detect a clinically significant change in Global EDE (0.45 points), assuming a standard deviation of Global EDE change scores of one (Hedeker et al., 1999) and also to detect a difference in mean weight gain of one BMI point which, based on previous research, would be clinically important to detect (Agras et al., 2000).

Statistical analyses were based on the intention-to-treat principle and were carried out by a biostatistician blind to treatment allocation (RDC). To account for missing data due to attrition or withdrawal from the trial, maximum likelihood imputation was implemented.

Continuous outcome data were analysed using linear mixed effects modelling, with restricted maximum likelihood estimation, adjusted or baseline values of the variable under investigation. Effect sizes were calculated using Cohen's d .

Chi-Square analyses were used for dichotomous categorical variables (1) achievement of healthy weight ($\text{BMI} > 18.5$); (2) having a Global EDE within 1 SD of Australian community norms (i.e., < 1.81 ; Mond et al., 2006) and (3) remission ($\text{BMI} > 18.5$, Global EDE < 1.8 and absence of binge eating/purging behaviours). For baseline data compared at one time point Chi-square tests (categorical data) and one way analysis of variance or independent samples median tests (continuous data) were used.

Site differences were examined for all primary and secondary outcomes.

Results

There were 557 enquiries regarding participation. One hundred and seventy one individuals were assessed for eligibility and 120 participants (97.5% female) were randomised between May 2010 and December 2013 (see **Figure 1**). Seventy two participants (60%) completed

treatment (progressed through all stages of treatment). Completion rates were 57.5% (23/40) for SSCM; 56.1% (23/41) for MANTRA and 66.7% (26/39) for CBT-E, $\chi^2(2) = 1.09, p = .58$. Thirty four (28.3%) dropped out (defined as non-mutual premature termination of treatment; 13 in SSCM, 10 in MANTRA, 11 in CBT-E, $\chi^2(2) = 0.66, p = .72$). Reasons for discontinuing included not wanting to continue with treatment (N=22), inability to attend (N=5), moving elsewhere (N=3), and increased work commitments (N=4). Fourteen participants (11.67%) were withdrawn (13 due to BMI dropping below 14 and being unable to recommence after 21 days [3 in SSCM, 8 in MANTRA, 2 in CBT-E]; one due to recommencing olanzapine [SSCM], $\chi^2(2) = 0.42, p = .12$). Eight participants (4 in SSCM, 2 in MANTRA, 2 in CBT-E) had inpatient admissions of < 21 days during treatment and then re-joined the trial. Seventy five percent of drop outs or withdrawals (N=35) occurred during the first half of treatment. There were no deaths. The median number of sessions attended was 24.5 (1-40) for SSCM, 25 (0-40) for MANTRA and 25 (0-40) for CBT-E (independent samples median test (2) = 0.5, $p = .78$). Of those participants who completed the end of treatment assessment (N=73), 63 (86.3%) completed the 12 month follow-up. There were no site differences with regard to treatment completion, $\chi^2(2) = 0.82, p = .66$.

Participant characteristics Baseline demographic and clinical characteristics are presented in **Table 1**. The mean age of the sample was 26.19 (SD = 9.47), median duration of illness was 4 years (IQR = 1-8) and over half (52.5%) of the sample had had at least one inpatient admission for AN. Mean pre-treatment BMI was 16.70 (SD = 1.22). The majority (82.5%) were Australian born and single (67.1%). Approximately half (44.2%) met diagnosis for AN-restricting subtype with the remainder being AN binge-purge subtype. Over one third met criteria for a depressive (38.3%) or anxiety disorder (35.8%) and 46.67% were currently taking psychotropic medication. There were no significant differences between the three treatment conditions on any of these characteristics ($ps > .05$) except that a

significantly smaller proportion of patients in SSCM (22.5% [9/40]) were currently depressed compared to CBT-E (51.3% [20/39]) and MANTRA (41.5% [17/41]), $\chi^2(2) = 6.75, p < .05$.

Participant expectations and treatment credibility

All treatments were rated highly on the CEQ at both mid-treatment and post-treatment with no significant differences in ratings among the three treatments (mid-treatment, $F(2, 69) = 1.64, p = .20$; post-treatment, $F(2, 64) = 2.43, p = .10$) (See **Table 1**).

Primary outcomes

Figure 2 shows mean estimated BMI at each assessment point for the three treatment arms (using imputed values). BMI increased significantly over time across all treatments, $F(3, 353.36) = 25.31, p < .001$ and the treatment by time interaction was not significant, $F(6, 353.36) = 1.66, p = .129$. CBT-E produced an estimated mean BMI increase of 2.10 (95% CI [1.65-2.79]) from baseline to post-treatment, 2.16 (95% CI [1.71-2.85]) from baseline to six month follow-up and 2.35 (95% CI [1.90-3.04]) from baseline to 12 month follow-up. The equivalent figures in SSCM were 1.58 (95% CI [1.14-2.25]), 1.71 (95% CI [1.28-2.38]) and 1.90 (95% CI [1.47-2.58]); and in MANTRA 1.37 (95% CI [0.62-1.71]), 1.35 (95% CI [0.59-1.69]) and 1.50 (95% CI [0.74-1.84]). At 12 month follow-up effect sizes for the differences in mean BMI were $d = 0.29$ for CBT-E vs MANTRA; $d = .21$ for CBT-E vs SSCM and $d = .08$ for SSCM vs MANTRA. The site by treatment by time interaction was non-significant, $F(16, 434.60) = 1.61, p = .07$.

Table 2 presents mean Global EDE score at each assessment point for the treatment arms. Global EDE decreased significantly over time across all treatments, $F(3, 190.11) = 23.38, p < .001$, with no significant treatment by time interaction, $F(6, 190.11) = .75, p = .61$. Once

again, the site by treatment by time interaction was non-significant, $F(16, 424.72) = 0.87$, $p = .60$.

Remission rates

The percentage of participants who achieved a BMI > 18.5 at each time point is shown in Figure 3. At 12 month follow-up a healthy weight had been achieved by 47.5% (19/40) in SSCM; 43.9% (18/41) in MANTRA and 59.0% (23/39) in CBT-E, with no differences among the treatments $\chi^2 = 1.97$, $df = 2$, $p = .37$. The proportion of participants achieving a 'normal' global EDE score (i.e., < 1.81) at 12 month follow-up did not differ across the treatments $\chi^2 = 1.73$, $df = 2$, $p = .42$ (SSCM = 25/40 [62.5%]; MANTRA = 21/41 [51.2%]; CBT-E = 19/39 [48.7%]), nor did the proportion of participants in remission (BMI > 18.5, Global EDE < 1.81 and absence of binge eating/purging behaviours); SSCM (32.5% [13/40]), MANTRA (22% [9/41]), CBT-E (30.8% [12/39]), $\chi^2 = 1.28$, $df = 4$, $p = .53$ (See Table 2). There were no significant site differences in the achievement of a healthy weight ($\chi^2 = 3.65$, $df = 2$, $p = .16$), normal Global EDE score, $\chi^2 = 0.27$, $df = 2$, $p = .87$) or remission ($\chi^2 = 0.47$, $df = 2$, $p = .66$). Of those participants who were in remission at end of treatment (31/120 [25.8%]), 25 (80.6%) were still in remission at one year follow-up (SSCM = 11/11; MANTRA = 7/11; CBT-E = 7/9) and the remaining six were in partial remission. Another six participants (SSCM = 1, MANTRA = 1, CBT-E = 4) who had not achieved full remission by end of treatment, continued to improve over time and did so by 12 month follow-up. Of those participants who completed the 12 month follow-up (N = 63), 23 (36.5%) reported attending additional treatment for their eating disorder since the end of treatment (SSCM = 6; MANTRA = 9; CBT-E = 8). This treatment most commonly took the form of less than monthly appointments with a psychiatrist and/or psychologist (N = 14). Three participants

received inpatient treatment during the follow-up period (SSCM = 1; MANTRA = 1; CBT-E = 1).

Depression, anxiety, stress and clinical impairment

On the DASS Depression subscale, there was a significant decrease in scores from baseline to 12 month follow-up across all treatment groups, $F(3, 250.72) = 10.21, p < .001$. The treatment by time interaction was also significant, $F(6, 250.72) = 2.40, p < .003$, due to differences in the trajectories of change (See **Table 2**). On both the Anxiety and Stress subscales of the DASS there was a significant decrease in scores over time in all treatments (Anxiety: $F(3, 218.13) = 6.37, p < .001$; Stress: $F(3, 226.70) = 8.66, p < .001$); and no treatment by time interaction (Anxiety: $F(6, 218.13) = .99, p = .43$; Stress: $F(6, 226.70) = 0.90, p = .50$). CIA scores also decreased significantly over time across all treatments, $F(3, 348.35) = 16.91, p < .001$, with no treatment by time interaction, $F(6, 348.35) = 1.48, p = .18$. The site by treatment by time interaction was non-significant for all of these secondary outcomes. Estimated means for the DASS and CIA at each time point are shown in **Table 2**.

Conclusion

We compared three outpatient treatments for adults with established AN, a notoriously treatment-resistant disorder. All three treatments were acceptable to patients and all resulted in improvements in weight and eating disorder psychopathology that were well maintained over a 12 month follow-up, although remission rates were low. There were no significant differences among the treatments with regard to BMI change over time or the achievement of a healthy BMI at 12-month follow-up. There was no difference between the treatments in the rate of improvement in eating disorder psychopathology, nor in the proportion of participants scoring in the normal range on the global EDE at 12 month follow-up. All treatments were

associated with a significant reduction in general psychopathology and psychosocial impairment.

Comparison of outcomes with previous clinical trials

Direct comparisons of our findings with those from previous trials need to be made with caution given the differences between the samples studied; differences in the way that the treatments have been implemented; and the different ways the findings have been analysed. Weight regain is one variable that is consistently reported and, as it is a central goal of treatment, it can be compared across the studies. For CBT-E, the percentage of participants achieving a healthy weight at post-treatment and 12 month follow-up (22 months post-randomisation) in the current study (53.8% and 59% respectively) is higher than the rates reported in the three-centre UK-Italy study (48%, 44%; Fairburn et al., 2013) and the mean BMI gain from baseline to end of treatment (2.1kg/m^2) is slightly greater (1.8kg/m^2). The mean BMI increase for CBT-E in this study is also greater than that reported for CBT-E in the ANTOP study (0.93 kg/m^2). For SSCM, the mean BMI gain from baseline to end of treatment in the current study (1.58kg/m^2) is similar to that reported in the first SSCM trial (1.5kg/m^2 ; McIntosh et al., 2005) and in the MOSAIC study (1.36kg/m^2 ; Schmidt et al., 2015). For MANTRA, however, mean post-treatment and follow-up BMI gains were less in the current study (1.37 kg/m^2 and 1.5 kg/m^2 respectively) than in the MOSAIC study (1.75kg/m^2 and 2.25 kg/m^2 respectively) (Schmidt et al., 2015). Thus, in the current trial, in regard to weight regain, CBT-E performed better than in previous studies, SSCM performed similarly and MANTRA performed less well.

Strengths and Limitations

The study had several strengths, a major one being that the treatments were delivered in ‘real world’ outpatient settings by therapists with varying degrees of experience. The assessments were conducted by assessors blind to treatment condition, statistical analyses were conducted by an independent biostatistician and attention was paid to measuring and ensuring therapist adherence (Andony et al., 2015).

The study also had limitations. The non-completion rate was high, although not unusually so for clinical trials in the field of eating disorders. The distribution of participants across sites was uneven, with more recruited to the Perth site than to Adelaide or Sydney. In addition, although therapist adherence to treatment protocols was measured, therapist competence was not assessed (Fairburn and Cooper, 2011) which may have been valuable given the fact that the majority of the therapists involved in this RCT had been primarily trained in cognitive behaviour therapy.

Final Comments

The findings of this study add to the evidence base for these three outpatient psychological treatments in the management of adults with AN. The treatments did not differ in their effectiveness. While significant improvements in weight and eating disorder symptoms were observed in all treatments, only half of the participants were in the healthy weight range at the 12 month follow-up and less than one third were in remission. The results of this study highlight just how difficult it is to achieve good outcomes with currently available treatments for adults with AN and underscore the need for continued efforts to improve outpatient treatments for this disorder.

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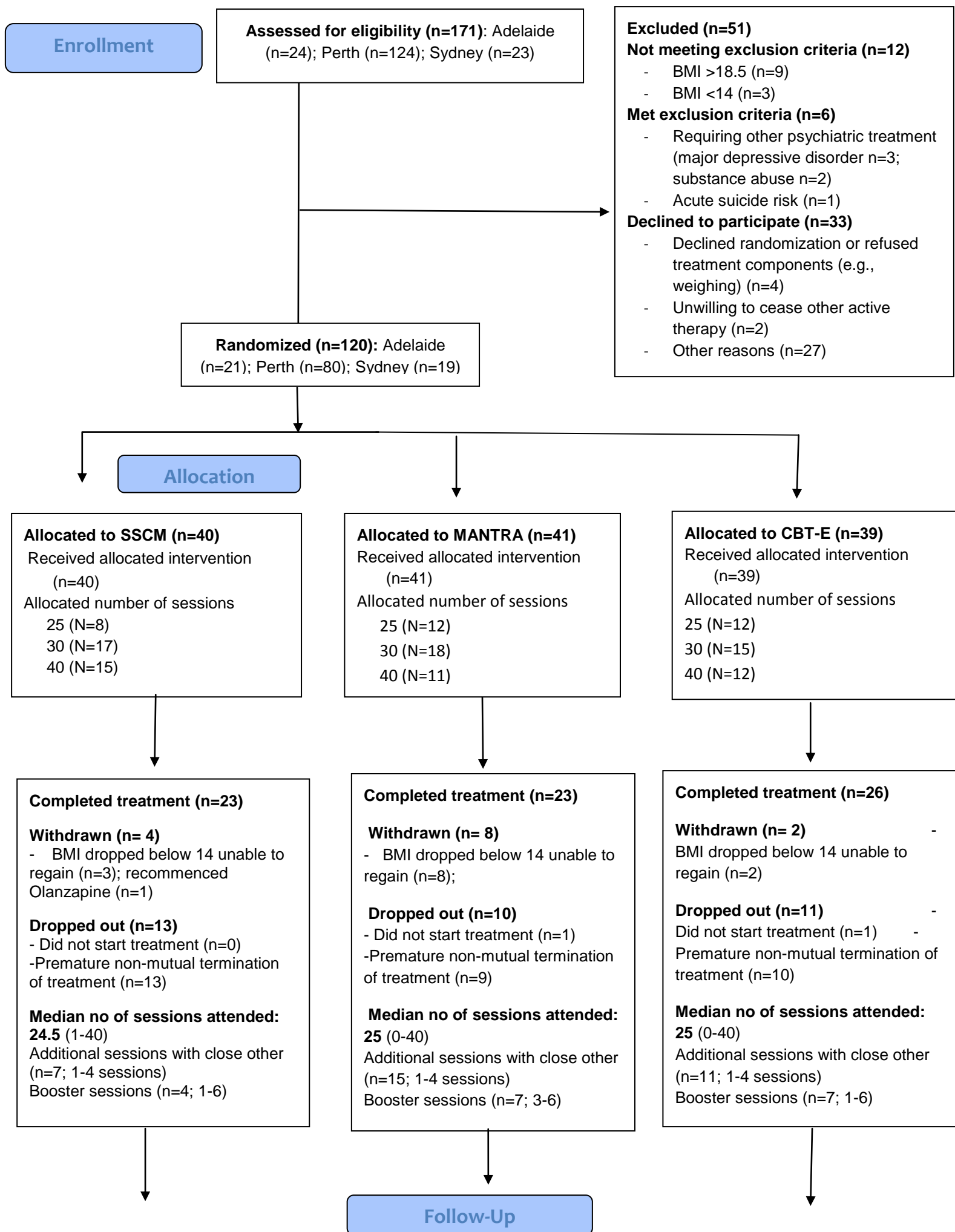
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Completed assessment

Baseline: n=40/40
Mid-treatment: 26/40
End of treatment: 23/40
6 month f/up: 19/40
12 month f/up: 19/40



Analysed (n=40)

Completed assessment

Baseline: n=41/41
Mid-treatment: 29/41
End of treatment: 24/41
6 month f/up: 19/41
12 month f/up: 21/41



Analysed (n=41)

Completed assessment

Baseline: n=39/39
Mid-treatment: 29/39
End of treatment: 26/39
6 month f/up: 18/39
12 month f/up: 23/39



Analysed (n=39)

Figure 2

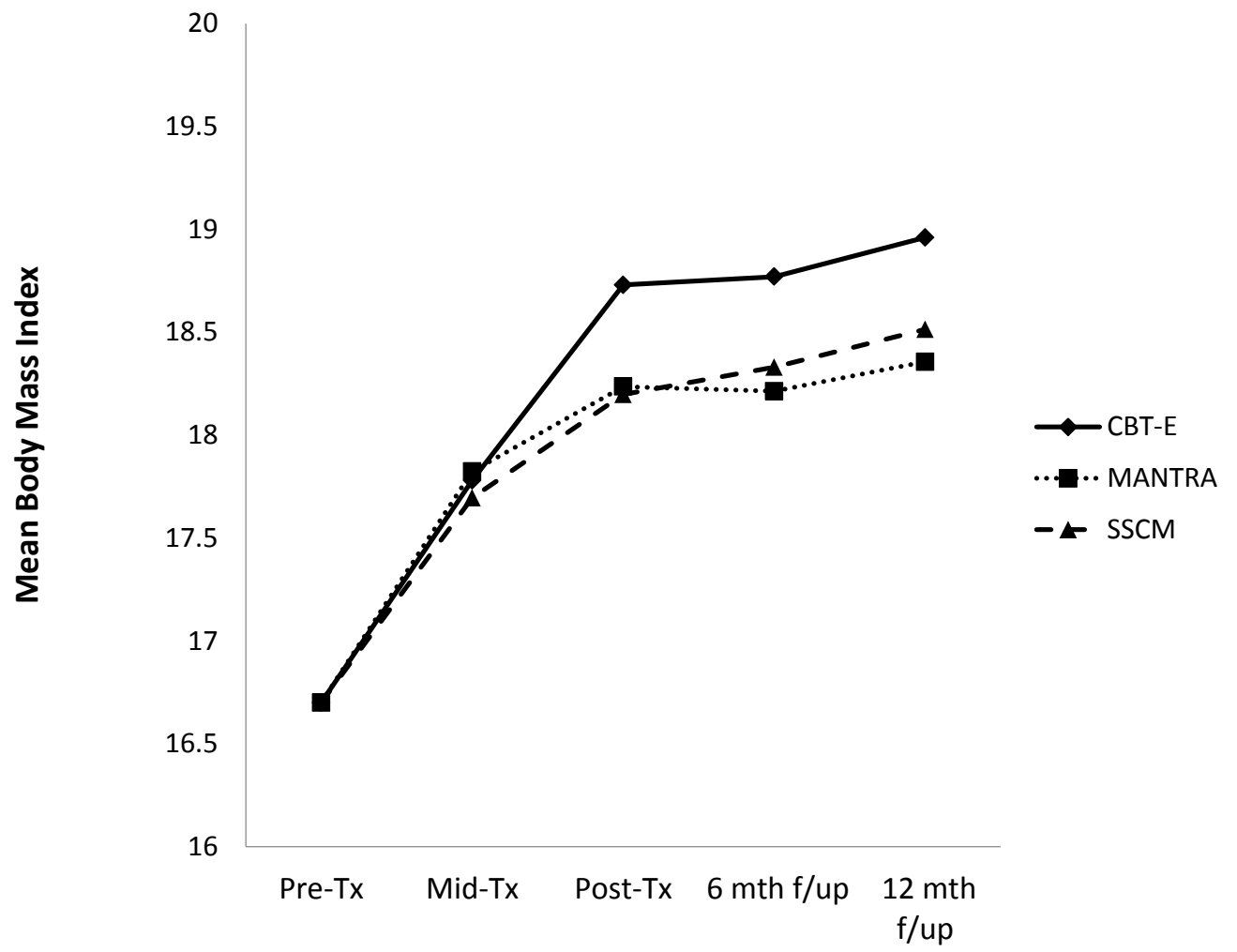


Figure 3

Percentage of participants achieving a healthy weight (BMI > 18.5) at each time point (using the full data set with imputed values).

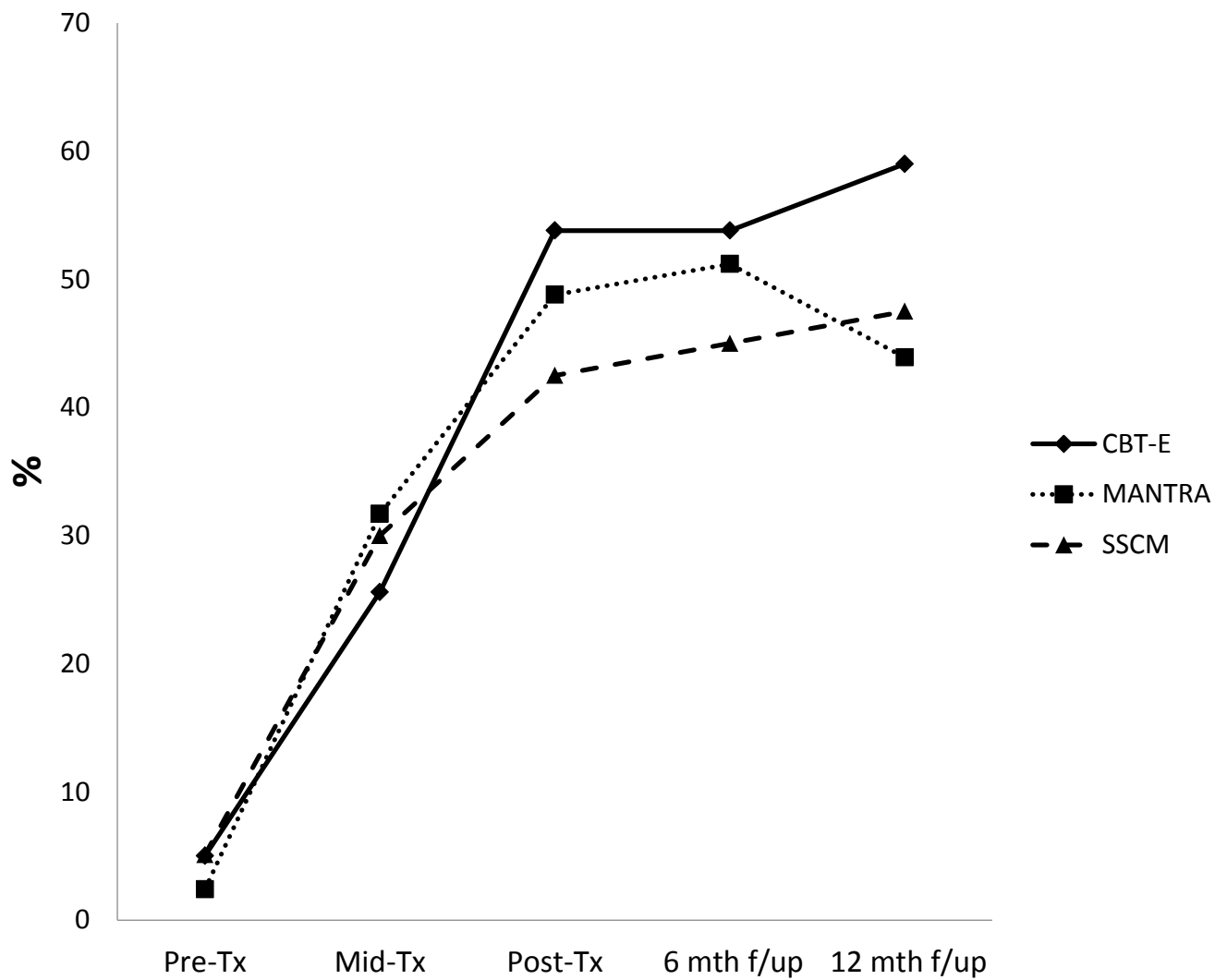


Table 1: Baseline characteristics of the sample

| Demographics | Entire sample N =120 | SSCM N=40 | MANTRA N=41 | CBT-E N=39 |
|------------------------------------|-------------------------|---------------|----------------|---------------|
| Age, years (mean [SD]) | 26.19 (9.47) | 28.44 (10.94) | 25.95 (9.00) | 24.18 (8.00) |
| Males: Females (n) | 5:115 | 3:37 | 1:40 | 1:38 |
| Country of birth | | | | |
| Australia | 99 (82.50) | 33 (82.50) | 33 (80.49) | 33(84.61) |
| U.K. | 9 (7.50) | 2 (5.00) | 4 (9.75) | 3 (7.69) |
| South Africa | 5 (4.17) | 1 (2.50) | 2 (4.88) | 2 (5.13) |
| Other | 7 (5.83) | 4 (7.50) | 2 (4.88) | 1 (2.56) |
| Qualifications (n [%]) | | | | |
| High School | 48 (40.00) | 16 (40.00) | 19 (46.34) | 14 (35.90) |
| Trade/Technical | 17 (14.17) | 2 (5.00) | 6 (14.63) | 8 (20.51) |
| Tertiary | 55 (45.83) | 22 (55.00) | 16 (39.02) | 17 (43.59) |
| Relationship status (n [%]) | | | | |
| Single (never married) | 80 (66.67) | 26 (65.00) | 25 (60.98) | 29 (74.36) |
| Married/de facto | 36 (30.00) | 14 (35.00) | 14 (34.15) | 8 (20.51) |
| Sep/Divorced/Widowed | 4 (3.33) | 0 (0) | 2 (4.8) | 2 (5.13) |
| Clinical characteristics | | | | |
| AN-Restricting subtype | 53 (44.17) | 21 (52.5) | 20 (48.78) | 12 (30.77) |
| AN-Binge/purge subtype | 67 (55.8) | 19 (47.5) | 21 (51.2) | 27 (69.2) |
| BMI, kg/m ² (mean [SD]) | 16.70 (1.22) | 16.58 (1.18) | 16.91 (1.11) | 16.59 (1.35) |
| BMI range (n[%]) | | | | |
| 14> 16 | 32 (26.7) | 8 (20) | 12 (29.3) | 12 (30.8) |
| 16 ≥ 17.5 | 50 (41.7) | 17 (42.5) | 18 (43.9) | 15 (38.5) |
| 17.5 ≥ 18.5 | 38 (31.7) | 15 (37.5) | 11 (26.8) | 12 (30.8) |

| | | | | |
|---|-------------|-------------|-------------|-------------|
| Duration of illness, years (median [IQR]) ^a | 4 (1-8) | 2 (1-8) | 5 (1-9) | 4 (1-7.5) |
| Previous inpatient eating disorder treatment (n [%]) | 63 (52.5) | 22 (55.00) | 19 (46.34) | 22 (56.41) |
| Global EDE (mean [SD]) | 3.32 (1.40) | 3.07 (1.30) | 3.38 (1.49) | 3.52 (1.40) |
| Current major depression (n [%]) ^b | 46 (38.33) | 9 (22.50) | 17 (41.46) | 20 (51.28) |
| Current suicidal ideation | 49 (40.83) | 11 (27.50) | 17 (41.46) | 21 (53.85) |
| Current Anxiety Disorder (n [%]) | | | | |
| GAD | 43 (35.8) | 14 (35.9) | 15 (36.6) | 14 (35.9) |
| Social Phobia | 29 (24.17) | 7 (17.50) | 8 (19.51) | 14 (35.90) |
| OCD | 22 (18.33) | 5 (12.50) | 7 (17.07) | 10 (25.64) |
| Panic disorder | 18 (15.00) | 4 (10.00) | 7 (17.07) | 7 (17.95) |
| Alcohol Dependence | 11 (9.17) | 1 (2.50) | 4 (9.76) | 6 (18) |
| Substance abuse | 5 (4.17) | 2 (5.00) | 2 (4.88) | 1 (2.56) |
| Current psychiatric medication (n [%]) | 56 (46.67) | 19 (48.70) | 21 (51.22) | 16 (41.02) |
| Treatment credibility and participant expectations | | | | |
| Mid-treatment CEQ (mean [SD]) | 6.64 (1.76) | 7.22 (1.66) | 6.27 (1.95) | 6.53 (1.59) |
| Post-treatment CEQ (mean [SD]) | 6.84 (1.76) | 7.58 (1.44) | 6.41 (2.00) | 6.69 (1.64) |

Note: all $ps > .05$; BMI = Body Mass Index; IQR= Interquartile Range; EDE = Eating Disorder Examination; GAD = Generalized Anxiety Disorder; OCD = Obsessive Compulsive Disorder; CEQ = Credibility/Expectations Questionnaire; ^a*Independent Samples Median Test* (2)=2.99, $p=.22$; ^b $\chi^2 = 6.75$ $df=2$, $p < .05$

Table 2

Estimated mean Global EDE, DASS and CIA scores at each time point for the three treatment arms (using full data set with imputed values).

| | Total Sample | | | | | SSCM | | | | | MANTRA | | | | | CBT-E | | | | |
|--|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|------------------|
| | Pre | Mid | EOT | 6 mth | 12 mth | Pre | Mid | EOT | 6 mth | 12 mth | Pre | Mid | EOT | 6 mth | 12mth | Pre | Mid | EOT | 6 mth | 12 mth |
| Global EDE Mean (SD) | 3.32 (1.40) | 2.43 (1.13) | 1.93 (1.13) | 1.94 (1.12) | 1.77 (1.13) | 3.32 (1.40) | 2.28 (1.10) | 1.79 (1.16) | 1.92 (1.17) | 1.59 (1.10) | 3.32 (1.40) | 2.32 (1.24) | 1.87 (1.19) | 1.85 (1.07) | 1.78 (1.19) | 3.32 (1.40) | 2.70 (1.13) | 2.13 (1.09) | 2.06 (1.14) | 1.93 (1.16) |
| Normal Global EDE score (< 1.81) n (%) | 22 (18.3) | 39 (32.5) | 51 (42.5) | 49 (40.8) | 55 (45.8) | 8 (20) | 15 (37.5) | 19 (47.5) | 17 (42.5) | 22 (55.0) | 8 (19.5) | 16 (39.0) | 18 (43.9) | 17 (41.5) | 18 (43.9) | 6 (15.4) | 8 (11.6) | 14 (35.9) | 15 (38.5) | 15 (38.5) |
| DASS- Dep Mean (SD) | 9.65 (6.57) | 7.17 (4.87) | 6.81 (4.80) | 7.75 (4.73) | 5.81 (4.82) | 9.65 (6.57) | 7.28 (5.01) | 5.91 (5.04) | 8.40(5.01) | 6.00 (5.00) | 9.65 (6.57) | 6.22 (4.79) | 6.90 (4.69) | 7.43 (4.56) | 5.69 (4.71) | 9.65 (6.57) | 8.01 (4.78) | 7.62 (4.67) | 7.42 (4.79) | 5.73 (4.72) |
| DASS-Anxiety Mean (SD) | 5.85 (4.73) | 4.05 (3.77) | 4.25 (3.88) | 3.50 (3.62) | 3.31 (3.02) | 5.85 (4.73) | 4.05 (3.81) | 3.96 (3.73) | 3.72 (3.94) | 3.48 (3.78) | 5.85 (4.73) | 3.45 (3.26) | 3.90 (3.21) | 3.04 (2.72) | 3.12 (3.15) | 5.85 (4.73) | 4.63(3. 80) | 4.88 (3.14) | 3.73 (3.39) | 3.33 (3.31) |
| DASS-Stress Mean (SD) | 11.58 (5.15) | 9.02 (4.77) | 7.85 (4.66) | 7.76 (4.53) | 7.54 (4.73) | 11.58 (5.15) | 8.95 (4.76) | 7.52 (4.72) | 7.89(4.75) | 7.62 (4.80) | 11.58 (5.15) | 8.45 (4.69) | 7.98 (4.54) | 7.49 (4.30) | 7.56 (4.51) | 11.58 (5.15) | 9.66 (4.87) | 8.04 (4.78) | 7.88 (4.58) | 7.43 (4.85) |
| CIA Mean (SD) | 32.82 (10.76) | 25.03 (13.89) | 21.34 (13.53) | 20.04 (12.99) | 20.81 (14.17) | 32.82 (10.76) | 24.47 (13.89) | 20.72 (13.98) | 20.30 (14.06) | 19.19 (14.41) | 32.82 (10.76) | 23.76 (14.29) | 20.94 (13.48) | 18.83 (12.22) | 21.22 (15.70) | 32.82 (10.76) | 26.87 (13.66) | 22.36 (13.44) | 20.99 (12.95) | 22.01 (13.52) |

Note: EDE = Eating Disorder Examination; DASS = Depression, Anxiety and Stress Scale; CIA = Clinical Impairment Questionnaire; Pre = pre-treatment (baseline); Mid = mid-treatment; EOT= end of treatment; 6 mth = six months post-treatment; 12 mth = 12 months post-treatment

